(k) Abbreviated new animal drug applications

The Secretary shall—

(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications, and

(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.

(June 25, 1938, ch. 675, §740, as added Pub. L. 108–130, §3, Nov. 18, 2003, 117 Stat. 1363; amended Pub. L. 110–316, title I, §103, Aug. 14, 2008, 122 Stat. 3510.)

AMENDMENT OF SECTION

For termination of amendment by section 108(a) of Pub. L. 110–316, see Effective and Termination Dates of 2008 Amendment note below.

TERMINATION OF SECTION

For termination of section by section 5 of Pub. L. 108–130, see Termination Date note below.

For savings provisions, see section 106 of Pub. L. 110–316, set out as a note under section 379j–11 of this title.

AMENDMENTS

2008—Subsec. (a)(1)(A)(i). Pub. L. 110–316, §§103(a)(1), 108(a), temporarily inserted '', except an animal drug application subject to the criteria set forth in section 360b(d)(4) of this title'' after ''for an animal drug application''. See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (a)(1)(A)(ii). Pub. L. 110–316, §§103(a)(2), 108(a), temporarily amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: ''A fee established in subsection (b) of this section for a supplemental animal drug application for which safety or effectiveness data are required, in an amount that is equal to 50 percent of the amount of the fee under clause (i).'' See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (b)(1). Pub. L. 110–316, §§103(b)(1), 108(a), temporarily substituted ''and supplemental and other animal drug application fees'' for ''and supplemental animal drug application fees'' and ''$3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.'' for ''$1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.'' See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (b)(2). Pub. L. 110–316, §§103(b)(2), 108(a), temporarily substituted ''$3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.'' for ''$1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.'' See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (b)(3). Pub. L. 110–316, §§103(b)(3), 108(a), temporarily substituted ''$3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.'' for ''$1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.'' See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (b)(4). Pub. L. 110–316, §§103(b)(4), 108(a), temporarily substituted ''$3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.'' for ''$1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.'' See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (c)(1). Pub. L. 110–316, §§103(c)(1)–(3), 108(a), temporarily redesignated par. (2) as (1), substituted ''The fee revenues shall be adjusted each fiscal year after fiscal year 2009'' for ''After the fee revenues are adjusted for inflation in accordance with paragraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004'' in introductory provisions, struck out '', as adjusted for inflation under paragraph (1)'' before period in subpar. (B), and struck out former par. (1) relating to inflation adjustment. See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (c)(2). Pub. L. 110–316, §§103(c)(2), (4), 108(a), temporarily redesignated par. (3) as (2) and substituted ''2013'' for ''2008'' in two places and ''2014'' for ''2009''. Former par. (2) redesignated (1). See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (c)(3) to (5). Pub. L. 110–316, §§103(c)(2), 108(a), temporarily redesignated pars. (4) and (5) as (3) and (4), respectively. Former par. (3) redesignated (2). See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (g)(3)(A) to (E). Pub. L. 110–316, §§103(d), 108(a), temporarily amended subpars. (A) to (E) generally. Prior to amendment, subpars. (A) to (E) read as follows:

''(A) $5,000,000 for fiscal year 2004;

''(B) $8,000,000 for fiscal year 2005;

''(C) $10,000,000 for fiscal year 2006;

''(D) $10,000,000 for fiscal year 2007; and

''(E) $10,000,000 for fiscal year 2008;''.

See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (g)(4). Pub. L. 110–316, §§103(e), 108(a), temporarily amended par. (4) generally. Prior to amendment, par. (4) read as follows: ''Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriations Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.'' See Effective and Termination Dates of 2008 Amendment note below.

EFFECTIVE AND TERMINATION DATES OF 2008 AMENDMENT

Amendment by Pub. L. 110–316 effective Oct. 1, 2008, with fees under this subpart to be assessed for all animal drug applications and supplemental animal drug applications received on or after Oct. 1, 2008, and ceases to be effective Oct. 1, 2013, see sections 107 and 108(a) of Pub. L. 110–316, set out as notes under section 379j–11 of this title.

TERMINATION DATE

Section not effective after Oct. 1, 2008, see section 5 of Pub. L. 108–130, set out as a note under section 379j–11 of this title.

§379j–13. Reauthorization; reporting requirements

(a) Performance report

Beginning with fiscal year 2009, not later than 60 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Animal Drug User Fee Amendments of 2008 toward expediting the animal drug development process and the review of the new and

supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

(b) Fiscal report

Beginning with fiscal year 2009, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(c) Public availability

The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) Reauthorization

(1) Consultation

In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of animal drug applications for the first 5 fiscal years after fiscal year 2013, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) veterinary professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) Prior public input

Prior to beginning negotiations with the regulated industry on the reauthorization of this subpart, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subpart; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) Periodic consultation

Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

(4) Public review of recommendations

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) Transmittal of recommendations

Not later than January 15, 2013, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) Minutes of negotiation meetings

(A) Public availability

Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) Content

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(June 25, 1938, ch. 675, § 740A, as added Pub. L. 110–316, title I, § 104, Aug. 14, 2008, 122 Stat. 3511.)

TERMINATION OF SECTION

For termination of section by section 108(b) of Pub. L. 110–316, see Effective and Termination Dates note below.

REFERENCES IN TEXT

Section 101(b) of the Animal Drug User Fee Amendments of 2008, referred to in subsec. (a), is section 101(b) of Pub. L. 110–316, which is set out as a note under section 379j–11 of this title.

EFFECTIVE AND TERMINATION DATES

Section effective Oct. 1, 2008, with fees under this subpart to be assessed for all animal drug applications and supplemental animal drug applications received on or

after Oct. 1, 2008, and ceases to be effective Jan. 31, 2014, see sections 107 and 108(b) of Pub. L. 110–316, set out as Effective and Termination Dates of 2008 Amendment notes under section 379j–11 of this title.

SUBPART 5—FEES RELATING TO GENERIC NEW ANIMAL DRUGS

TERMINATION OF SUBPART

For termination of subpart by section 204 of Pub. L. 110–316, see Termination Date notes set out under sections 379j–21 and 379j–22 of this title.

§ 379j–21. Authority to assess and use generic new animal drug fees

(a) Types of fees

Beginning with respect to fiscal year 2009, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Abbreviated application fee

(A) In general

Each person that submits, on or after July 1, 2008, an abbreviated application for a generic new animal drug shall be subject to a fee as established in subsection (b) for such an application.

(B) Payment

The fee required by subparagraph (A) shall be due upon submission of the abbreviated application.

(C) Exception for previously filed application

If an abbreviated application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an abbreviated application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) Refund of fee if application refused for filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any abbreviated application which is refused for filing.

(E) Refund of fee if application withdrawn

If an abbreviated application is withdrawn after the application was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application after the application was filed. The Secretary shall have the sole discretion to refund the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

(2) Generic new animal drug product fee

Each person—

(A) who is named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product which has been submitted for listing under section 360 of this title, and

(B) who, after September 1, 2008, had pending before the Secretary an abbreviated application or supplemental abbreviated application,

shall pay for each such generic new animal drug product the annual fee established in subsection (b). Such fee shall be payable for the fiscal year in which the generic new animal drug product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the generic new animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each generic new animal drug product for a fiscal year in which the fee is payable.

(3) Generic new animal drug sponsor fee

(A) In general

Each person—

(i) who meets the definition of a generic new animal drug sponsor within a fiscal year, and

(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application, a supplemental abbreviated application, or an investigational submission,

shall be assessed an annual fee established under subsection (b). The fee shall be paid on or before January 31 of each year.

(B) Amount of fee

Each generic new animal drug sponsor shall pay only 1 such fee each fiscal year, as follows:

(i) 100 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with more than 6 approved abbreviated applications.

(ii) 75 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with more than 1 and fewer than 7 approved abbreviated applications.

(iii) 50 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with 1 or fewer approved abbreviated applications.

(b) Fee amounts

Except as provided in subsection (a)(1) and subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be established to generate fee revenue amounts as follows:

(1) Total fee revenues for application fees

The total fee revenues to be collected in abbreviated application fees under subsection (a)(1) shall be $1,449,000 for fiscal year 2009, $1,532,000 for fiscal year 2010, $1,619,000 for fiscal year 2011, $1,712,000 for fiscal year 2012, and $1,809,000 for fiscal year 2013.

(2) Total fee revenues for product fees

The total fee revenues to be collected in generic new animal drug product fees under subsection (a)(2) shall be $1,691,000 for fiscal year